Worcestershire Acute Hospitals NHS Trust

Antenatal management of women at risk of preterm delivery

Interim guideline (March 2019)

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Approved by:	Maternity Governance Meeting	
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Key Amendments

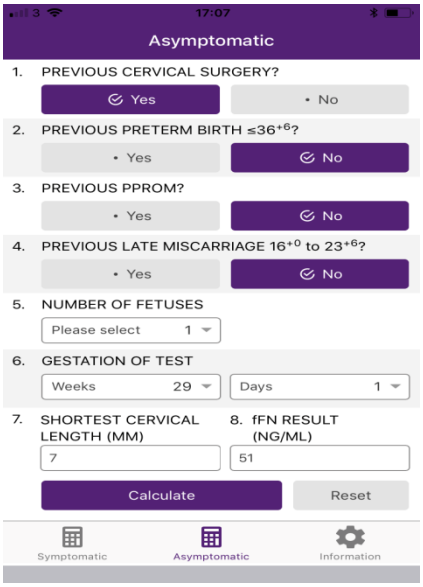
Date	Amendments	Approved by

Who to screen?

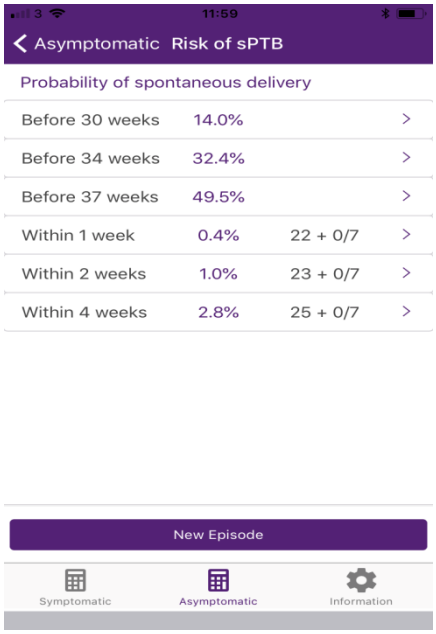
1. Prior LLETZ >10mm
2. Prior cone biopsy
3. Women who have had LLETZ/Cone where the depth is unknown
4. Prior late miscarriage 16-23+6/40
5. Prior spontaneous preterm birth ≤34/40
6. Prior PPROM

How to screen?

1. Organise a departmental cervical length scan from 18/40. Repeat at 22/40.
2. If the cervix remains long at 22/40 (i.e. ≥25mm) discharge.
3. If the cervical length is <25mm offer the patient quantitative fetal fibronectin (fFN).
4. If the patient accepts fFN, refer the patient (preferably on the same day) to Worcester DAU.
5. The fFN can be taken by the on-call registrar and the result obtained, using the monitor in the ANC.
6. DAU/ANC staff is trained to use the fFN machine.
7. Use the QuIPP APP (free to download to all mobile devices or access on desktop) to generate a risk of delivery within the next week, 2 weeks or 4 weeks. See screen shot below.



8. Counsel the patient according to the risks generated. See screen shot below.



9. Patients' interpretation of risk is very individual.
10. There is no cut off for when you should absolutely agree to place a cerclage however a 5% risk of delivery might be perceived as significant.
11. Cerclage can be offered if less than 24/40.
12. Steroids can be offered to patients at higher risk of delivery (>5%) from 23/40 following patient counselling.

13. Women with a short cervix should not receive a cerclage based on scan alone.

Other management points for women at risk of preterm delivery

1. Offer patients with a **shortening cervix** Aspirin 75mg/OD/PO and Cyclogest 400mg/PR or PV/nocte. Explain to the patient that both are considered to be safe in pregnancy. There is adequate evidence to suggest that these may be a useful intervention for women at risk of early delivery.
2. Offer aspirin 75mg/OD/PO to all women with a history of prior preterm delivery starting at c.12/40.
3. Stress the importance of smoking and the strong association with preterm delivery. Refer to smoking cessation where appropriate and check carbon monoxide levels regularly.
4. Recommend to patients that they minimise psycho-social stress and consider stopping work. This is especially important where the cervix is already shortening <25mm. There is no evidence to support the benefit of total bed rest.
5. Patients with a poor history of mid-trimester loss (i.e. <24/40) consistent with cervical incompetence (i.e. painless cervical dilatation) can be offered a prophylactic cerclage and should be seen no later than 14/40 in a general ANC following first trimester screening for counselling.

How to take a fibronectin (fFN) swab

1. Quantitative fFN can be taken from 18/40.
2. Avoid gel on the speculum as it will increase the risk of false positives.
3. Also beware taking a swab if the patient has bled or has had recent sexual intercourse.
4. Using the swab, sample the posterior fornix for 10 seconds.
5. Place the swab into the fluid medium provided.
6. This sample is now ready to be analysed by the Hologic fFN reader.

How to calibrate the fFN reader

1. Machine must be calibrated every morning by clinic staff.
2. Switch on the Hologic machine (switch at the back of the machine).
3. Input your user name (ok to use your usual log in for the desktop).
4. The cassette for calibration is in the locked cupboard in the clean utility.
5. To calibrate the machine, press the central square marked calibrate.
6. Then insert the calibration cassette and press next.
7. The machine will calibrate, providing you with a “pass” sticker.
8. The machine is now ready to use.

9. If there is a failure to calibrate, the machine cannot be used and the Hologic Rep will need to be contacted.

How to test a patient sample

1. Once the machine has been calibrated, press “test patient”.
2. Input your user details as mentioned above.
3. Using the bar code reader scan the LOG number on the side of the box containing the fFN test cassettes.
4. Press the button for “numbers”.
5. Input the patient hospital number and press “next”.
6. Insert the test cassette into the machine until you hear a click.
7. Using the pipette provided, administer 200mcl to the test well.
8. Press start and the machine will start to measure the sample.
9. The test takes 10 minutes to complete after which a result will automatically print.
10. Using the QuIPP APP, combine the fFN result with the cervical length to generate the risk of delivery, as explained above.
11. Counsel the patients regarding the risk of delivery over the next 1 week, 2 weeks and 4 weeks.
12. Document onward plan in the notes

Appendix 1

QuIPP

The QUiPP app is a clinical decision-making tool with the potential to revolutionize preterm birth prediction for women with symptoms of threatened preterm labour as well as asymptomatic high-risk women. Accurate diagnosis of preterm labour is desirable in order to prevent the maternal and fetal risks incurred to the majority of women who are over-managed, without missing true cases.

This application has been designed for health, allied health and health research professionals who look after pregnant women to calculate individualised % risks scores of delivery within pre-specified clinically relevant timeframes. It is designed to be used with women as an educational tool and to arrive at shared decisions regarding the management of their pregnancy.

It is designed for use in two clinical settings:

1. For management of asymptomatic women at high-risk for preterm birth (delivery before 37 weeks' gestation) who are attending preterm surveillance clinics
2. For management of women with symptoms suggestive of abnormal or premature uterine activity (e.g. abdominal pain, contractions, tightenings).

It relies on a relevant clinical history having been taken regarding the woman's risk factors for preterm birth and her current symptoms. It relies on existing point-of-care testing: quantitative fetal fibronectin (fFN) sampling of the cervico-vaginal fluid and/or transvaginal ultrasound cervical length (CL) measurements. Therefore the user is expected to have significant midwifery or obstetric experience in order to use QUiPP app or is working closely with a team-member who does.

How to counsel

Using a 5% risk of delivery within 7 days according to the QUiPP App as the threshold for intervention, 9/9 women with threatened preterm labour would have been treated correctly, giving a sensitivity of 100% (one-sided 97.5% CI, 66.4%) and a negative predictive value of 100% (95% CI, 98.9–100%). The positive predictive value for delivery within 7 days was 30.0% (95% CI, 11.9–54.3%) for women presenting before 30 weeks and 20.0% (95% CI, 4.3–49.1%) for women presenting between 30 and 34 weeks. If this 5% threshold had been used to triage women presenting between 24 and 29+6 weeks, 89.4% (n=168) of admissions could have been safely avoided, compared with 0% for a treat-all strategy. No true case of preterm labour would have been missed, as no woman who was assigned a risk of <10% delivered within 7 days.

For women with threatened preterm labour, the QUiPP App can accurately guide management at risk thresholds for sPTB of 1%, 5% and 10%, allowing outpatient management in the vast majority of cases. A treat-all approach would not have avoided admission for any woman, exposed 188 mothers and their babies to unnecessary hospitalization and steroid administration and increased the burden on network and transport services owing to unnecessary in-utero transfers. Prediction of sPTB should be performed before 30 weeks to determine management until there is evidence that such a high level of unnecessary intervention, as suggested by the treat-all strategy, does less harm than the occurrence of rare false negatives.

References:

1. The QUiPP App: a safe alternative to a treat-all strategy for threatened preterm labour. H. A. WATSON, J. CARTER, P. T. SEED, R. M. TRIBE and A. H. SHENNAN Ultrasound Obstet Gynecol. 2017 Sep;50(3):342-346. doi: 10.1002/uog.17499. Epub 2017 Jul 30.